Company: Chengdu Xinjin Shifeng Medical Apparatus & Instrument Co., Ltd.
Product: Shifeng Piston Syringe with or without needle
Address: No.46, 7th group, Wanjie Village, Xinping town, Xinjin County, Chengdu City, P. R. China
Tel: +86(028)85757683, Fax: +86(028)85157183, Email: xjshifeng2011@163.com

K111841

MAR - 1 2012

510 (K) Summary

Device Name

Proprietary Name: Shifeng Disposable Syringe with or without needle

Classification Name: Piston Syringe
21 CFR, Section 880.5860
21 CFR, Section 880.5570
Classification: Class II

Common Name: Piston Syringe with or without needle

Intended Use

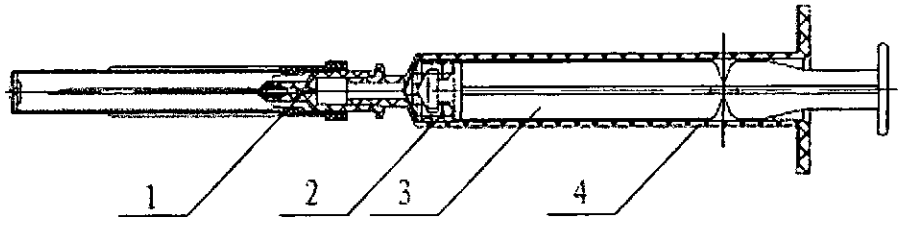
The Shifeng Disposable Syringe with or without needle are intended to be used to inject fluid into, or withdraw fluids from, part of the body below the surface of the skin.

Device Description

The ShiFeng Disposable Syringe is a sterile, single-use device consisting of a needle attached to a syringe. The ShiFeng Disposable Syringe manufactured by Chengdu Xinjin Shifeng Medical Apparatus & Instruments Co., Ltd., China is substantially equivalent to the IMC Piston syringe with Hypodermic Lumen Needle manufactured by IMC and cleared under K102969. (Refer to Pic 1)

The device consists of a metal tube that is sharpened at one end and the other end joined to a female connector (hub) designated to mate with a male connector (nozzle) of a piston syringe consisting of a calibrated hollow barrel and a movable plunger

XinJin Shifeng buy the Shangdong Qiaopai needle (510(K) 073705) and do the assembly with the syringe together.



1. Needle 2. Piston 3. Plunger 4. Barrel

Pic 1

Predicate Device Name and 510(K) No.:

IMC Piston syringe with Hypodermic Lumen Needle manufactured by IMC and cleared under K102969

Substantial Equivalence

The ShiFeng Disposable Syringe manufactured by Chengdu Xinjin Shifeng Medical Apparatus & Instruments Co., Ltd., China is substantially equivalent to IMC Piston syringe with Hypodermic Lumen Needle manufactured by IMC and cleared under K102969.

Principle of Operation/Technology

Both devices are operated manually

Materials

The materials used in the ShiFeng Disposable Syringe manufactured by Chengdu Xinjin Shifeng Medical Apparatus & Instruments Co., Ltd., China are same as the predicate devices, which do not raise any new issues of safety or effectives.

Parts	Material	Specification
Barrel	Polypropylene	K4912
Plunger	Polypropylene	V30G
Lubricant	Polydimethysiloxane	HC-SS36
Piston	Synthetic rubber	SK1
Primary Package Material	Medical rubberizing Dialysis paper and PE	65g/m^2 Medical rubberizing Dialysis paper
Needle	Qiaopai needle (510(K) 073705)	

Specifications

Syringe	Needle
1ml Luer Slip_sterile	0.45 (26G)
2ml Luer Slip_sterile	0.50 (25G)
3ml Luer Slip_sterile	0.60 (23G)
5ml Luer slip_sterile	0.60 (23G) , 0.7 (22G)
10ml Luer Slip_sterile	0.90 (20G) , 1.2 (18G)

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Performance

The following tests were performed on the Shifeng Disposable Syringe manufactured by Chengdu Xinjin Shifeng Medical Apparatus & Instrument Co., Ltd, China in accordance with ISO 7886-1:1993/Cor. 1: 1995:

ISO Clause No.	Test Items
5	Cleanliness
6	Limits for acidity or alkalinity
7	Limits for extractable metals
8	Lubricant
9	Tolerance on graduated capacity
10.1	Scale
10.2	Numbering of scale
10.3	Overall length of scale to nominal capacity line
10.4	Position of scale
11.1	Dimensions
11.2	Finger grips
12.1	Design
12.2	Fit of piston in barrel
12.3	Fiducial line
13.1	Conical fitting
13.1	Conical fitting
13.2	Position of nozzle on end of barrel
13.2	Position of nozzle on end of barrel
13.3	Nozzle lumen
14.1	Dead space
14.2	Freedom from air and liquid leakage past piston
14.2	Freedom from air and liquid leakage past piston
15.1	Primary container
15.2	Secondary container
16.1	Primary container
16.2	Secondary container
16.3	Storage container
16.4	Transport wrapping

None of the data raises any new issues of safety and effectiveness.

The Shifeng Disposable Syringe with or without needle manufactured by Chengdu Xinjin Shifeng Medical Apparatus & Instruments Co., Ltd., China is substantially equivalent to IMC Piston syringe with Hypodermic Lumen Needle manufactured by IMC and cleared under K102969.

Comparison table:

The Shifeng Disposable syringe with or without needle manufactured by XinJin Shifeng in Sichuang, China is substantially equivalent to the IMC Piston syringe with Hypodermic Lumen Needle manufactured by IMC and cleared under K102969.

Element of Comparison	Subject Device	Claimed SE Device
Syringe Type	Piston Syringe Classification II, FMF	Same
Intended Use (s)	are intended to be used to inject fluid into or withdraw fluids from, the body.	Same
Principle of Operation	The operation principle is pushing or pulling the plunger to inject fluid into or withdraw fluids from the body, suitable for human skin, muscle, intravenous injection, etc	Same
Specific Drug Use	NO	Same
Length	Various sizes complying with ISO 7886-1, 11.1	Same
Barrel Diameter	1ml: 4.65-4.70mm 2ml: 8.85-8.90mm 3ml: 9.00-9.05mm 5ml: 12.40-12.45mm 10Ml: 14.95-15.00mm	Similar
Tip Type	Centric	Same
Volume	Size various from 1ml to 10 ml	Same
Nozzle Type	Slip tip	Same
Barrel Marking Specs	Complying with ISO7886-1	Same
Gradations legibility	Legible	Same
Lubricant amount / cm2	Not exceed 0.25mg	Same
Barrel Transparency	Transparent	Same

Delivery Accuracy	Complying with ISO 7886-1, 10.1 ~10.4	Same
Reuse Durability	Not applicable, single use device	Same
Biocompatibility	Complying with ISO 10993	Same
Materials		
• Lubricant	Polydimethylsiloxane	Similar See Section Ⅷ, A.1, page 5
• Barrel	Polypropylene	Same
• Plunger	Polypropylene	Same
• Piston	Synthetic rubber	Similar See Section Ⅷ, A.2, page 9
Labeling	Complying with ISO7886-1: 1993	Same
Sterilization	ETO, ISO 11135 compliance	Same
Needle & Needle Cover	Shangdong Qiaopai needle 510(K) 073705	Similar

Additional Safety Information

The sterilization conditions are validated according to ISO 11135-1:2007 to provide a Sterility Assurance Level (SAL) of 10^{-6}.

Ethylene Oxide residual levels after 7 days aeration resulting from EtO sterilization will not exceed the maximum daily dose levels proposed 10993-7:2008 and indicated as follows:

Ethylene Oxide	1.501ug/device (Lot. 20100301) 10.9ug/device (Lot. 20110926)
ECH	10.9ug/device (Lot. 20110926)

The device's materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #g95-1 (5/1/95): Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation

and Testing. Results of the testing demonstrate that the blood contacting materials are biocompatible.

Conclusion

The Shifeng Disposable Syringe with or without needle manufactured by XinJin Shifeng in Sichuang, China is substantially to the Disposable Hypodermic Syringe manufactured by IMC Piston syringe with Hypodermic Lumen Needle manufactured by IMC and cleared under K102969 with respect to intended use, design, technology/principles of operation, materials and performance. Differences between the devices do not raise any new issues of safety or effectiveness.

Date Prepared: 2011-11-15

Prepared by:

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Xing long Tian 2011.11.15

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR - 1 2012

Mr. Xinglong Tian
Quality Assurance & Regulatory Affairs Vice President
Chengdu Xinjin Shifeng Medical Apparatus & Instrument Company, Limited
No.46, 7th Group
Wanjie Village, Xinping Town
Xinjin County
Chengdu City
P.R. CHINA

Re: K111841
Trade/Device Name: Shifeng Disposable Syringe with or without Needle
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF / FMI
Dated: February 16, 2012
Received: February 16, 2012

Dear Mr. Tian:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K111841

Device Name: Shifeng Disposable Syringe with or without needle

Indications for Use:

The Shifeng Disposable Syringe with or without needle are intended to be used to inject fluid into, or withdraw fluids from, part of the body below the surface of the skin.

(PLRASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

3/1/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

(Optional Format 1-2-96)

510(k) Number: K111841